

REMARKS

This amendment and remarks are in response to the Office Action mailed August 8, 2006 (the "Office Action"). Applicants have canceled claim 53 in the present amendment. Claims 1-53 and 61-80 have already been canceled. Thus, claims 54-60 and 81-110 are pending. No new matter has been added.

Information Disclosure Statement

On July 11, 2006, applicants filed an information disclosure statement with five pages on Forms-1449. In the Office Action, the Examiner returned initialed copies of only three of the pages. Applicants request that the Examiner consider the references listed on the forms (listing 19 references, beginning with Alonso *et al.*) and return an initialed copy.

Applicants acknowledge the withdrawal of the following rejections: the rejection of claims 54-60, 81-93, 95-106, and 108-110 under 35 U.S.C. § 112, first paragraph, as lacking written description; the rejection of claims 54-60, 81-90, 93, 97, 109, and 110 as anticipated by Barnett *et al.* (*Vaccine*, 8:869-873, 1997; "Barnett"); the rejection of claims 54 and 96 as obvious over Andre *et al.* (*J. Virol.*, 72(2):1497-1503, 1998; "Andre"); and the rejection of claim 54, in part, and claims 91, 92, 94, 97, and 98 as obvious over Barnett and Gao *et al.* (*J. Virol.*, 70(3): 1651-1667, 1996 ("Gao 1").

35 U.S.C. § 112, First Paragraph; Enablement

Claim 53 has been rejected as allegedly lacking enablement. Although applicants disagree, claim 53 has been canceled. Therefore, this rejection is moot.

Rejections Under 35 U.S.C. § 103

Claims 54-60 and 81-110 have been rejected as allegedly unpatentable over Barnett, Gao 1 *et al.*, Gao *et al.* (*AIDS Res. Hum. Retrovir.*, 10(11): 1359-1368, 1994; "Gao 2"), and Andre.

The Office Action states (at pages 4-5):

Barnett teaches a method of inducing immune responses using priming immunization with a DNA plasmid vaccine containing envelope genes of primary strains...Barnett does not teach the use of multiple HIV envelope DNAs and proteins of different clades as immunogens.

Gao teaches a panel of envelope genes from HIV-1 primary isolates of clade A to G. Gao also suggests that the panel of envelope genes from HIV-1 clade A to G should prove valuable for AIDS vaccine development efforts targeted against a broader spectrum of viruses.

Andre teaches an HIV gp120 DNA vaccine whose gene codons are optimized for improved expression in human cells...It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Barnett, Gao and Andre in order to increase the breadth of reactivity of a HIV vaccine cross [sic] genetic clades and increase the immunogenicity of the vaccine. One would have been motivated to do so, given the suggestion by Gao that envelope genes from HIV-1 clade A to G should prove valuable for AIDS vaccine development efforts targeted against a broader spectrum of viruses.

Applicants respectfully traverse this rejection. The Office Action relies on "Gao" for the suggestion to use envelope genes of multiple clades. Two references naming Gao as the first author were cited in this rejection. In the above-quoted passage, it is unclear to which Gao article the Office Action refers. Applicants discuss both Gao 1 and Gao 2 here. Gao 1 and Gao 2 describe the cloning and analysis of envelope genes from different HIV-1 clades. The authors PCR-amplified envelope genes from peripheral blood of infected patients in different epicenters of infection and characterized the sequences and *in vitro* expression of the genes.

Gao 1 states that "[t]he panel of env constructs described here should prove valuable for future structure-function studies of naturally occurring envelope glycoproteins as well as AIDS vaccine development efforts targeted against a broader spectrum of viruses" (Gao 1, abstract, last sentence). Gao 2 states that their data "should assist in the design and evaluation of effective vaccines against HIV-1" (Gao 2, abstract, last sentence). These are very general statements as to the potential future utility of the data reported in the references. However, the existence of a panel of envelope sequences does not amount to a teaching or suggestion to employ nucleic acid compositions encoding envelope glycoproteins from multiple HIV types or genetic clades in the methods as claimed.

Neither Gao 1 and Gao 2 describes or even suggests any specific vaccination methods, much less ones in which the claimed compositions are used. The indefinite statements that Gao's constructs "should prove valuable" for vaccine development efforts is not a clear suggestion to practice any particular vaccination method. The requisite motivation is lacking in these references. Barnett and Andre also fail to teach uses of a plurality of nucleic acids as claimed. In view of the foregoing, applicants request withdrawal of the rejection of claims 54-60 and 81-110 under 35 U.S.C. § 103.

CONCLUSION

Applicants submit that the claims are in condition for allowance and such action is requested. Please apply the Petition for One-Month Extension of Time fee and any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 17738-003001.

Respectfully submitted,

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